REMARKS

Claims 7 and 24-26 are currently pending and under consideration.

Rejection under 35 U.S.C. § 103(a)

Claims 7 and 24-26 are rejected under 35 U.S.C. § 103(a), allegedly, as being obvious over Liang *et al.*, 1998, Immunol. 93:462-468 ("Liang"). In particular, the Examiner alleges that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to administer the TCR Vβ8.1 peptide to humans to combat cytokine irregularities associated with aging and that a reasonable expectation of success was also present.

Preliminarily, Applicants wish to note for the record that the Examiner's rejection is seemingly improper based on the previously made rejection for lack of enablement, which up until now has been made continuously by the Examiner since the start of prosecution on the merits in February 2002. A total of three office actions, dated February 15, 2002, November 5, 2002 and March 25, 2004, were issued by the Examiner and in each of which the pending claims were rejected as not being enabled by the disclosure of the specification. Applicants argued successfully that the claimed invention was indeed enabled. In fact, in the penultimate office action dated August 15, 2005, the Examiner withdrew the enablement rejection and indicated that the claims were allowable once a simple lack of clarity rejection under Section 112, second paragraph, was addressed.

At that time, and even previous thereto, Liang was of record and was considered by the Examiner, as evidenced by the Examiner's initial on the List of References Cited form accompanying the office action dated March 24, 2004. Applicants note that Liang was submitted in an Information Disclosure Statement as Reference AD on December 5, 2003. Now, however, the Examiner recites Liang as though it had never been made of record

and bases the current rejection under Section 103 on Liang. Applicants consider this new Section 103 rejection over a reference already made of record to be unfair as Applicants fail to understand how an invention that was allegedly not enabled now be obvious over the same art of record. It is well settled law that what is not enabled cannot be obvious. Applicants respectfully request that this Section 103 rejection be withdrawn and the previous indication that the claims are allowable be reinstated.

As to the legal merits of the rejection, under the current law, prior art references cannot render a claim obvious unless the Patent and Trademark Office provides evidence that the references meet a three-part test for *prima facie* obvious. To begin with, the prior art reference or references must provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant." *See In re Kotzab*, 217 F.3d 1365, 1370, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000); *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 2005 WL 1355127, at *4, 75 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 2005). Where one reference is relied upon by the PTO, there must be a suggestion or motivation to modify the teachings of that reference. *See In re Kotzab*, 217 F.3d at 1370, 55 U.S.P.Q.2d at 1316-17. Where an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references. *See WMS Gaming Inc. v. International Game Technology*, 184 F.3d 1339, 1355, 51 U.S.P.Q.2d 1385, 1397 (Fed. Cir. 1999); *Princeton Biochemicals, Inc.*, 2005 WL 1355127, at *4, 75 U.S.P.Q.2d at 1054; *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1334, 63 U.S.P.Q.2d 1374, 1387 (Fed. Cir. 2002). Second, the prior art references cited by the Patent and Trademark Office must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. *See In re Dow Chemical*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988); *Boehringer Ingelheim Vetmedica, Inc.*, 320 F.3d 1339, 1354, 65 U.S.P.Q.2d 1961, 1971 (Fed. Cir. 2003);

Noelle v. Lederman, 355 F.3d 1343, 1352, 69 U.S.P.Q.2d 1508, 1516 (Fed. Cir. 2004). Further, "[b]oth the suggestion and the reasonable expectation of success 'must be founded in the prior art, not in the applicant's disclosure.'" *Noelle*, 355 F.3d at 1352, 69 U.S.P.Q.2d at 1515-16 (quoting *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991)). Finally, the Patent and Trademark Office must show that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims. *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473, 43 U.S.P.Q.2d 1481, 1490 (Fed. Cir. 1997); *Litton Systems, Inc. v. Honeywell, Inc.*, 87 F.3d 1559, 1569, 39 U.S.P.Q.2d 1321, 1327 (Fed. Cir. 1996).

Applicants submit that Liang does not suggest the use of the peptide in humans as Liang deals exclusively with aged mice and even refers only the earlier studies in mice with retrovirus-induced immune abnormalities. At best, Liang is merely an invitation to experiment, *i.e.*, obvious to try. This "obvious to try" is not a legitimate test of obviousness. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). *See also Novo Nordisk A/S v. Becton Dickinson and Co.*, 304 F.3d 1216, 1219 (Fed. Cir. 2002). As there is no suggestion of the use of the peptide in humans, the Examiner has not met the first of the three required parts of the test for obviousness. Therefore, this Section 103 rejection is in error and must be withdrawn.

CONCLUSION

Applicants respectfully request that the above-made remarks of the present response be entered and made of record in the file history present application.

Applicants request that the Examiner call the undersigned at (212) 326-3939 if any questions or issues remain.

Respectfully submitted,

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Enclosures